Section 2 Summary of Safety and Effectiveness

Date: July 28, 2006

Submitter: GE Medical Systems *Information Technologies*
8200 West Tower Avenue
Milwaukee, WI 53223 USA

AUG - 4 2006

Contact Person: Adrienne Lenz
Quality Engineer
GE Medical Systems *Information Technologies*
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Device: Trade Name: Twelve Lead Transformation Function, "12RL"

Common/Usual Name: 12RL

Classification Names:

21 CFR 870.2300 Cardiac monitor	74DRT
21 CFR 870.2340 Electrocardiograph	74DPS
21 CFR 870.1025 Detector and Alarm, Arrhythmia	74DSI
21 CFR 870.1425 Programmable diagnostic computer	74DQK
21 CFR 870.2920 Transmitters and Receivers, Electrocardiograph, Telephone	74DXH

Predicate Device:

1 K992595	1 EASI	1 Philips
2 K030738	2 TruST	2 Siemens
3 K964750	3 Marquette Eagle 4000	3 GE Medical Systems *Information Technologies*

Device Description: The 12RL feature is intended to reconstruct electrocardiograph (ECG) signals such that a 12-lead ECG presentation can be made when at least six electrodes are attached to a patient. These 12-lead ECGs may be 10 second records or continuous recordings suitable for ST segment trending.

Intended Use: The GE 12RL program generates a 12-lead ECG report from a subset of the electrodes used to acquire a standard 12 lead ECG. Four of the precordial channels of the 12-lead ECG (V2, V3, V4, V6) are not acquired from the patient; rather, they are reconstructed from information that is directly recorded in the other channels of the 12-lead ECG.

The four signals generated by the GE 12RL program are similar but not identical to the standard 12-lead ECG. All ECG data generated via 12RL are clearly identified as to which channels have been synthesized.

The GE 12RL program is intended for use in a monitoring environment. Computerized measurements may be generated from these data; however, a computerized interpretation will not.

The product is intended for use in the general adult population ranging from healthy subjects to patients with cardiac and/or non-cardiac abnormalities.

The product is to be used in conjunction with the patient's clinical history, symptoms, and other diagnostic tests for final clinical judgment.

Technology: The 12RL technology is based on linear equations as is used by the predicate devices. Therefore there is no change in technology.

Test Summary: The 12RL complies with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the 12RL program:

- Risk Analysis
- Requirements Specification Review
- Code Inspections
- Software Verification and Validation Testing

Conclusion: The results of these measurements demonstrated that the 12RL program is as safe, as effective, and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 4 2006

GE Healthcare Information Technologies
c/o Ms. Adrienne Lenz
Regulatory Affairs Specialist
9900 Innovation Drive
Wauwatosa, WI 53226

Re: K060307
Trade Name: 12 Lead Transformation Function, "12RL"
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: DRT
Dated: July 28, 2006
Received: July 31, 2006

Dear Ms. Lenz:

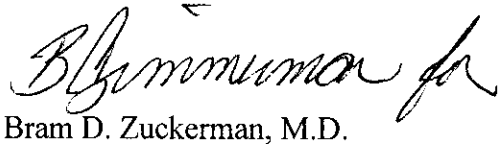
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K060307

Device Name: 12 RL Algorithm

Indications For Use:

The GE 12RL program generates a 12-lead ECG report from a subset of the electrodes used to acquire a standard 12 lead ECG. Four of the precordial channels of the 12-lead ECG (V2, V3, V4, V6) are not acquired from the patient; rather, they are reconstructed from information that is directly recorded in the other channels of the 12-lead ECG.

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The product is to be used in conjunction with the patient's clinical history, symptoms, and other diagnostic tests for final clinical judgment.

Prescription Use__X__ OR Over-The-Counter Use____
(Per 21 CFR 801.109 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K060307